

WHAT IS CLAIMED IS:

1. An implantable valve for a bodily passage of tubular shape, comprising:
 - a plurality of leaflets, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one or another of the plurality of leaflets,
 - 5 the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to at least substantially occlude fluid flow in a second direction opposing the first direction,
 - 10 the outer edge of each of the plurality of leaflets adapted to engage a wall of the bodily passage oriented at least partially longitudinally therealong and at least partially circumferentially therearound such that the leaflet extends along said bodily passage away from the inner edges in said direction,
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2. The vascular valve of claim 1, wherein at least a portion of the body of the leaflet being flexible at least proximate the free edge thereof.
3. The implantable valve of claim 1 wherein said outer edge of each of the plurality of leaflet at least partially comprises a frame.
- 20 4. The implantable valve of claim 3 wherein the outer edges of the plurality of leaflets include overhanging material, the overhanging material extending beyond the frame to which the plurality of leaflets are attached.
5. The implantable valve of claim 3 wherein said frame comprises a wire to and around which the bodies of the leaflets are secured.

6. The implantable valve of claim 1 wherein the covering includes two leaflets such that when the frame is substantially flattened, it assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.
- 5 7. The implantable valve of claim 3 wherein the body and the frame of each leaflet comprises an integral, one-piece member.
8. The implantable valve of claim 1 wherein said integral, one-piece member is molded into a generally flat shape.
- 10 9. The implantable valve of claim 7 wherein said integral, one-piece member is molded into a serpentine shape.
10. The implantable valve of claim 1 wherein the covering comprises an extracellular collagen matrix.
11. The implantable valve of claim 6 wherein the extracellular collagen matrix includes small intestinal submucosa.
- 15 12. The implantable valve of claim 1 comprising two leaflets.
13. The implantable valve of claim 1 wherein the frame is adapted to assume a plurality of configurations, the plurality of configurations includes a generally flat configuration, whereby the frame in the generally flat configuration is generally diamond-shaped.
- 20 14. The implantable valve of claim 1 comprising at least three leaflets.

15. The implantable valve of claim 1 further including at least one barb to anchor the implantable valve to the wall of the bodily passage.

16. The implantable valve of Claim 15 wherein the at least one barb is integral projection extending from the frame.

5 17. The implantable valve of Claim 1 wherein the inner edge of at least one of the plurality of leaflets includes a flap, the flap configured to be extendable over the inner edge of adjacent one of the plurality of leaflets when the valve is in the closed condition.

10 18. The implantable valve of Claim 1 further including a circumferentially constraining mechanism that restricts radial expansion of the implantable valve in within the bodily passage.

15 19. An implantable valve for a bodily passage of tubular shape, comprising:
a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and
extending in a opposite direction therefrom, each of the plurality of legs terminating at the second end of the implantable valve such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,
a plurality of leaflets, each leaflet comprising a covering that includes
20 one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured 5 such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough, while the plurality of leaflets are further adapted to seal against one another to at least substantially reduce retrograde flow.

20. The implantable valve of Claim 19 wherein the frame includes metal.

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21. The implantable valve of Claim 20 wherein the frame comprises a superelastic alloy.

22. The implantable valve of Claim 20 wherein the frame comprises a continuous wire structure.

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23. The implantable valve of Claim 19 wherein the frame comprises a flattened structure, such as if formed from a sheet of metal.

24. The implantable valve of 19 wherein the frame includes at least one open section therealong, the at least one open section including a portion of the covering, the covering constraining the frame, thereby providing a bridge 20 across the at least one open section.

25. The implantable valve of Claim 19 wherein the covering comprises a biomaterial.

26. The implantable valve of Claim 25 wherein the biomaterial includes an extracellular collagen matrix.

27. The implantable valve of Claim 26 wherein the extracellular collagen matrix comprises tissue derived from small intestinal submucosal tissue.

5 28. The implantable valve of Claim 19 wherein the frame comprises a polymeric material.

27. The implantable valve of claim 19 wherein the frame is formed into the serpentine configuration.

10 28. The implantable valve of Claim 19 wherein the frame comprises a bioabsorbable material.

29. The implantable valve of claim 19 wherein the frame is adapted to assume a plurality of configurations, a first configuration of the plurality of configurations being a generally flat plane.

15 30. The implantable valve of claim 19 wherein the covering includes two leaflets such that when the frame in the generally flat configuration generally assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.

20 31. The implantable valve of claim 30 wherein the frame generally assumes a rounded shape without well-defined corners when the frame is in the generally flat configuration, the covering comprising two leaflets.

32. The implantable valve of claim 19 wherein the frame includes at least three legs.

33. The implantable valve of claim 32 including three legs lying approximately 120° with respect to one another, the leaflets thereof so 5 arranged such that the opening therethrough generally assumes a triangular shape when the frame is in the flat configuration prior to deployment.

34. The implantable valve of Claim 32 including four legs lying approximately 90° with respect to one another, the leaflets thereof so 10 arranged such that the opening therethrough generally assumes a square shape when the frame is in the flat configuration prior to deployment.

35. The implantable valve of Claim 19 further including a circumferentially constraining mechanism attached about at least one valve leg, the circumferentially constraining mechanism configured to restricts radial expansion of the implantable valve in within the bodily passage.

15 36. An implantable vascular valve comprising:

a covering including first and second oppositely facing curvilinear surfaces when positioned across a vascular opening and also including at least a first arcuate outer edge that exerts pressure against, and at least forms a partial seal with, a vascular wall when positioned thereagainst;

20 wherein the covering also includes an orifice extending through the oppositely facing curvilinear surfaces;

wherein the orifice is in a closed position blocking fluid flow therethrough when fluid is applied to the first oppositely curvilinear surface with the valve positioned across the vascular opening; and

wherein the orifice is in an open position permitting fluid flow therethrough when fluid is applied to the second oppositely curvilinear surface with the valve positioned across the vascular opening.

3A 37. An implantable vascular valve comprising:

5 a covering including first and second oppositely curvilinear facing surfaces when positioned across a vascular opening and also including at least a first resilient arcuate outer edge that exerts pressure against, and at least forms a partial seal with, a vascular wall when positioned thereagainst;

10 wherein the covering also includes an orifice extending through the oppositely facing curvilinear surfaces;

wherein the orifice is in a closed position blocking fluid flow therethrough when fluid is applied to the first oppositely curvilinear surface with the valve positioned across the vascular opening; and

15 wherein the orifice is in an open position permitting fluid flow therethrough when fluid is applied to the second oppositely curvilinear surface with the valve positioned across the vascular opening.

40 38. An implantable vascular valve comprising:

20 a covering including first and second oppositely facing curvilinear surfaces when positioned across a vascular opening and also including at least a first arcuate outer edge that exerts pressure against, and at least forms a partial seal with, a vascular wall when positioned thereagainst;

wherein the covering also includes an orifice extending through the oppositely facing curvilinear surfaces and has at least a flexible portion cooperating with the orifice;

25 wherein the orifice is in a closed position blocking fluid flow therethrough when fluid is applied to the first oppositely curvilinear surface with the valve positioned across the vascular opening; and

wherein the orifice is in an open position permitting fluid flow therethrough when fluid is applied to the second oppositely curvilinear surface with the valve positioned across the vascular opening.

41 39. The valve of claim 38, wherein the flexible portion is adjacent the
5 orifice.

42 40. An implantable vascular valve comprising:
a covering including first and second oppositely facing curvilinear surfaces when positioned across a vascular opening and also including at least a first arcuate outer edge that exerts pressure against, and at least 10 forms a partial seal with, a vascular wall when positioned thereagainst;

wherein the covering also includes an orifice extending through the oppositely facing curvilinear surfaces and has at least a first and a second flexible portion cooperating with the orifice;;

15 wherein the orifice is in a closed position blocking fluid flow therethrough when fluid is applied to the first oppositely curvilinear surface with the valve positioned across the vascular opening; and

wherein the orifice is in an open position permitting fluid flow therethrough when fluid is applied to the second oppositely curvilinear surface with the valve positioned across the vascular opening.

43 20 41. The valve of claim 40, wherein the first and second flexible portions are adjacent the orifice.

44 42. An implantable medical device comprising:

a covering including first and second oppositely facing curvilinear surfaces when positioned across a vascular opening and also including at

least a resilient first arcuate outer edge that exerts pressure against, and at least forms a partial seal with, a vascular wall when positioned thereagainst; wherein the covering is constrained in a predetermined direction, whereby at least the pressure exerted against the vascular wall is distributed 5 substantially uniformly.

43. A multiple-sided intraluminal medical device comprising:
a single frame having a closed circumference with an aperture therethrough, said closed circumference having a plurality of sides, adjacent ones of said plurality of sides and interconnecting bends, the frame adapted 10 to assume a plurality of configurations, a fist configuration of the plurality of configurations being in a generally flat plane;
wherein, the frame, having been formed in a first shape, is so constrained into a second shape such that at least selected ones of the plurality of bends, having been resiliently formed into a first angle between 15 respective adjacent ones of the plurality of sides, are maintained at a second angle such that the frame is constrained against its bias to return to the first shape such that the at least selected ones of the plurality of bends would reassume the first angle between the adjacent ones of the plurality of sides.

44. The device of claim 43 wherein the frame is constrained by a flexible covering attached to the respective adjacent ones of the plurality of sides. 20

45. The device of claim 43 wherein the frame includes a continuous length of a resilient material that has been attached to itself such that the at least selected ones of the plurality of bends are constrained into the second angle.

46. An implantable valve for a bodily passage of tubular shape, comprising:

a frame having a pair of legs, the frame being radially expandable against the walls of the bodily passage,

a plurality of leaflets comprising material derived from small intestinal submucosa, each leaflet thereof having a body extending from a wall-engaging outer edge to a free edge proximate a corresponding free edge of at least one or another of the plurality of leaflets, the wall-engaging outer edge of the leaflet being at least partially reinforced by one of the plurality of legs of the frame,

the free edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along said bodily passage, and further cooperable to engage each other sufficiently to at least substantially occlude fluid flow in a second direction opposing the first direction,

the outer edge of each said leaflet adapted to engage a wall of the bodily passage oriented at least partially longitudinally therealong and at least partially circumferentially therearound such that the leaflet extends along said bodily passage away from the free edges in said second direction,

at least a portion of the body of each said leaflet being flexible at least proximate the free edge thereof, and

the plurality of leaflets having a first shape when unconstrained and relaxed and being compressible into a second shape of smaller general size for delivery to a treatment site in said bodily passage, and being expandable at said treatment site upon delivery thereto for the outer edges of said leaflets to sealingly engage the passage wall while the free edges of the bodies of all said leaflets are moveable into and out of engagement with each other in response to fluid flow.

47. An implantable valve for a bodily passage of tubular shape, comprising:

a self-expanding frame that includes a pair of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the pair of legs terminating about the second end of the implantable valve such that the

5 pair of legs generally and collectively assume a serpentine configuration along the circumference of a bodily passage when situated therein;

10 a plurality of barbs, at least one barb attached to each of the pair of legs, at least one of the barb including a terminal projection, the terminal projection configured to releasably engage with a delivery system for deployment of the implantable valve into the bodily passage;

15 a pair of leaflets, each leaflet comprising tissue derived from an extracellular collagen matrix, each of the leaflets including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced the frame, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily

passage,

20 wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with the other of the plurality of leaflets to define an opening that permits positive flow of fluid therethrough, while the pair of leaflets are further adapted to seal against one another to at least substantially reduce retrograde flow.